

REMARKS

The Official Action of October 9, 2003, and the prior art cited and relied upon therein have been carefully studied. The claims in the application remain as claims 1-16, and these claims (including presently non-elected claim 16) define patentable subject matter warranting their allowance. Applicant accordingly respectfully requests favorable reconsideration and allowance.

Applicant hereby respectfully affirms the provisional election, made with traverse, of Group I, presently claims 1-15.

Applicant respectfully submits that the restriction requirement is improper because the process as claimed cannot be practiced using another device, let alone one which is "**materially different**"; and the apparatus as claimed cannot be used to practice another process, let alone one which is "**materially different**". The PTO says that the process can be practiced by hand. But this is clearly incorrect, because the process explicitly calls for **using the device of claim 1**. In this regard, please note operation (c) which calls for "introducing the stool specimen into the kit according to **claim 1**".

How can this operation be carried out without using the kit of claim 1? The answer is that it cannot, and the requirement is incorrect.

Another reason exists for withdrawing the requirement. In this regard, MPEP 803, second paragraph, **requires** the PTO to search and examine an entire application, **even in those cases where the requirement is correct**, if it would not constitute a serious burden to do so. In the present case, because the method is so closely tied to the device, there would be no serious burden to examine claim 16 along with claims 1-15, even though claim 16 may be separately classified.

Accordingly, applicant respectfully requests withdrawal of the requirement and examination on the merits of claim 16 along with elected claims 1-15.

Filed herewith is a replacement drawing for a correction to Fig. 1, i.e. the cap is now labeled "13" instead of "B", the latter of which was incorrect. Approval and entry of the replacement sheet of drawing are respectfully requested.

Claims 1-15 have been rejected under §102 as anticipated by Wuske USP 6,375,896 (Wuske). This rejection is respectfully traversed.

Claim 1 has now been amended to define the housing as being "separate from said vessel", support being found in Fig. 1, where it can be seen that the vessel 11 is separate from the housing 10, as it must be. In addition, that the housing is separate from the vessel is also to be inferred from applicant's specification in general, and at page 5, lines 23-26.

Claim 1 has been further amended at the end thereof to recite the result, which in any event is inherent from claim 1 as originally drafted.

Wuske discloses a swab analyzer in which the housing (1) and the application zone (2) (which the examiner equates with the vessel of the invention) are one integral unit. This feature is a basic element of the invention of Wuske, and is emphasized several times (see e.g. col. 1, lines 34-36 and 54-56; col. 2, lines 31-35). Accordingly, Wuske does not anticipate claim 1, and therefore does not anticipate any of applicant's claims, because of this first distinction of applicant's housing being separate from the vessel, whereas they are combined into one integral unit in Wuske.

As second distinction appears in part (b) of claim 1, where it is recited that the substrate comprises "at least one zone containing food antigens,...." There is no such disclosure in Wuske.

Part (b) of claim 1 also recites that the housing further comprises "reagents for producing a visually detected reaction when an antibody-food antigen complex is formed,...". This is not disclosed by Wuske which does not describe a test kit for detection of a food allergy in an individual by using food antigens to detect the presence of antibodies against the food antigens in a stool specimen.

Applicant's claims are novel. Withdrawal of the rejection under §102 is in order and is respectfully requested.

Claims 1-15 are again rejected under §102 as anticipated by Wuske, or alternatively as obvious under §103 from Wuske. These rejections are respectfully traversed.

First, insofar as the same claims are again rejected over the same reference under the same statutory provision, §102, applicant does not understand how this rejection differs from the other rejection discussed immediately above. Applicant has pointed out above that Wuske does not anticipate claim 1, and therefore does not anticipate any of applicant's claims. In other words, all of applicant's claims define novel subject matter over Wuske for the reasons pointed out above.

Next, to the extent that the stated rejections are presented in the alternative, applicant respectfully submits

that such rejections are inconsistent. If a prior art citation anticipates a claim, then that claim cannot be obvious from that citation. If such citation makes obvious the subject matter of the claim, then such citation does not anticipate the claim. It can be either one, but not both. The rejections are inconsistent. In the present case, applicant's claims are neither anticipated nor made obvious by Wuske.

Insofar as the rejection is based on §103, applicant respectfully notes that the various difference between claim 1 and Wuske are non-obvious:

(1) As noted above, the housing of the present invention contains food antigens, which are not at all mentioned in Wuske. There is nothing in the prior art which would have led the person of ordinary skill in the art to modify Wuske so as to provide food antigens in the housing.

(2) As noted above, the vessel and the housing are separate entities in the present invention, whereas in Wuske they are one integral unit. This is an important distinction. As a result of the separation between the housing and the vessel in the present invention, the dilution of the sample is carried out **prior** to its application to the housing. This provides a different function, i.e. in applicant's invention

control is exercised over the preparation of the sample as to time, temperature, amount of diluent, fractionation, etc.

To the contrary, in Wuske, dilution occurs **after** application of the sample to the housing. Thus, the diluted sample will flow automatically to the analytical compartment, without the user being able to control the sample being analyzed. Therefore, the simple separation of the vessel from the housing, contrary to any teaching of Wuske, serves a functional purpose which improves the performance of the test kit. As there is no teaching of such a change, this constitutes a nonobvious departure from Wuske.

(3) The rejection states that it "would have been obvious to test a stool sample because stool samples contain proteins (allergens) which will react with immunological components". However, the kit of the invention tests stool samples for the presence of **antibodies** against food antigens, and not for allergens (see e.g. page 4, lines 23-25).

In general, Wuske does not contemplate nor describe a test kit for detection of a food allergy in an individual by using food antigens to detect the presence of antibodies against the food antigens in a stool specimen, and there is no evidence of any teaching to modify Wuske to reach the claimed subject matter.

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Withdrawal of the rejections based on §§102 and 103  
is requested.

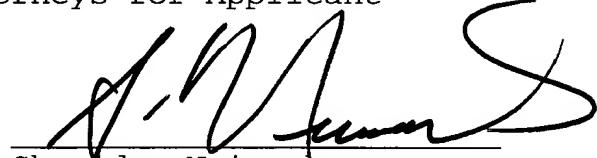
The prior art documents made of record and not  
relied upon have been noted, along with the implication that  
such documents are deemed by the PTO to be insufficiently  
pertinent to warrant their application against any of  
applicant's claims.

Favorable reconsideration and allowance are  
earnestly solicited.

Respectfully submitted,

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Amendments to the Drawing

Attached hereto is a replacement drawing sheet.

Approval and entry are respectfully requested.